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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,142	06/29/2000	Joel Cherry	5443.424-US	7060

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/607,142	CHERRY ET AL.	
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 Sheets* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *3 Sheets* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments filed 08 August 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 41-57. Claims 1-40 have been cancelled by the amendment filed 08 August 2003.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 56 and 57 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the intended goal of constructing a variant of a parent maltogenic alpha-amylase such that the variant possesses maltogenic alpha-amylase activity (i.e. preamble of claim 41), does not reasonably provide enablement for the construction of a variant(s) such that it is void of maltogenic alpha-amylase activity, via the additional steps in dependent claims 56 and 57. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, claims 56 and 57 recite the following steps: "d) repeating steps b) and c) recursively; e) making alterations each of which is an insertion, a deletion or a substitution of an amino acid residue at one or more positions other than c)" wherein the recursive processing and/or alterations at one or more positions (i.e. insertion, deletion or substitution) maybe performed to the extent that a constructed variant is no longer one that has any properties in common with the parent maltogenic alpha-amylase. One of ordinary skill in the art would not know how to use variants that did not have enzymatic activity.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as necessitated by amendment.

VAGUE AND INDEFINITE

Claim 40 (line 14) and all claims dependent therefrom recite the limitation "which can be accommodated in the structure" which is vague and indefinite. Applicants' state the following in the amendment filed 08 August 2003:

> "The term "accommodated" is used in its plain and ordinary meaning in the art to refer to an acceptable fit, and the phrase "accommodated in the structure" accordingly refers to the amino acid changes made to the parent enzyme, and whether such changes fit in the structure of the enzyme. A clear example of the meaning of the term would be that as a result of the amino acid change, the structure is not sterically disrupted such that the enzyme is no longer able to bind the substrate.

Applicants pointed the Examiner to Exhibit 6 (Steric Constraints In Model Proteins, 23 December 1997, page 6, last paragraph) to support the term "accommodated". The reference to Exhibit 6 states:

> "Our studies show that the most encodable structures are indeed compact and that the smaller residues are more easily accommodated within the core of the protein...The considerations presented here suggest that the smaller polar amino acids (Thr, Ser) ought to have a larger propensity for being buried than the larger ones (Lys, Glu, and Arg) and this is indeed observed in studies of natural proteins"

However, this is viewed as only one manner in which a substitution can be accommodated in the structure. Applicants have argued by way of definition the terminology of "accommodated in the structure" to refer to amino acid changes that fit in the structure of the enzyme, indicating one example of such fit to mean the structure is not sterically disrupted and is capable of binding to the substrate. However, the phrase "accommodated in the structure" is broadly encompassing to the extent it is unclear what changes would fit the structure of the enzyme. Further, Applicants did not indicate a page and line number in the specification for support of "accommodated", "accommodated in the structure", "such changes fit in the structure of the enzyme", or "the structure is not sterically disrupted such that the enzyme is no longer able to bind to the substrate". Therefore, it remains unclear by what limitation Applicants refer to as "accommodated", wherein "accommodated" implies a degree of accommodation (i.e. value, criteria, etc). Even Applicants' argument of acceptable fit indicates that a level of fit (unspecified in claims or specification) is required. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 54-57 recite the step(s) "repeating steps b) and c) recursively" and "repeating steps a)-g) recursively" (claim 57, line 7) which is vague and indefinite. The step is unclear as to the limitation provided for by "repeating". For example, if steps b) and c) are repeated recursively the number of times such process is repeated is not defined (i.e. point at which one would stop the repeating process). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 55-56 recite the step "preparing the variant resulting from steps a)-d)"(claim 55)/"preparing the variant resulting from steps a)-e)" which is vague and indefinite. It is unclear

whether Applicants' intend for the preparation of the variant: 1) after the completion of step 'e'; or 2) after the completion of each step (i.e. a, b, c, etc). If Applicants' intend the latter such language is found confusing, for example, at the conclusion of step 'a' no variant is constructed. Clarification of the metes and bounds, via clearer claim language, is requested.

ACTION IS FINAL, AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: October 30, 2003

Examiner Initials: CSM

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
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